Medentika GmbH
% Jennifer Jackson
Sr. Director of Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01801

April 15, 2024

Re: K223113
Trade/Device Name: Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM TiBases, Medentika Multi-unit Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 9, 2024
Received: April 10, 2024

Dear Jennifer Jackson:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223113

Device Name

Medentika Abutment System

Indications for Use *(Describe)*

Medentika abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

Medentika abutments for the Dentsply Sirona Astra Tech OsseoSpeed EV 3.0mm and TX 3.0mm implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

Implant System Compatibility Series (Series / Implant System / Implant diameter / Platform Diameters or Implant Connection):

Standard Abutment:

Medentika series of the medical device	**Manufacturer of the implant system**	**Compatible Implant system**	**Implant Diameters (mm)**	**Platform Diameters (mm)**
EV-Series	DENTSPLY Implants	ASTRA TECH OsseoSpeed® EV	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4
S-Series	DENTSPLY Implants	ASTRA TECH OsseoSpeed® TX	3.0	3.0
R-Series	ZimVie	Tapered Screw-Vent®	3.3, 3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7

Temporary Abutment:

Medentika series of the medical device	**Manufacturer of the implant system**	**Compatible Implant system**	**Implant Diameters (mm)**	**Platform Diameters (mm)**
S-Series	DENTSPLY Implants	ASTRA TECH OsseoSpeed® TX	3.0	3.0

MedentiLOC Abutment:

Medentika series of the medical device	**Manufacturer of the implant system**	**Compatible Implant system**	**Implant Diameters (mm)**	**Platform Diameters (mm)**
OT-Series	OSSTEM Implant HiOssen Implant	TS System ET-System	3.5, 4.0, 4.5, 5.0, 6.0, 7.0 3.5, 4.0, 4.5, 5.0, 6.0, 7.0	Mini, Regular

Type of Use (Select one or both, as applicable)

☒Prescription Use (Part 21 CFR 801 Subpart D) ☐Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K223113

Device Name

Medentika CAD/CAM TiBases

Indications for Use *(Describe)*

Medentika TiBase CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. Medentika TiBase is intended for use with the Straumann® CARES® System. All digitally designed copings and/or crowns are intended to be sent to Straumann for manufacture at a validated milling center.

Medentika abutments for the Nobel Biocare Nobel Active®* 3.0mm, Dentsply Sirona Astra Tech OsseoSpeed EV®* 3.0mm and TX®* 3.0mm implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.
Implant System Compatibility Series (Series / Implant System / Implant diameter / Platform Diameters or Implant Connection):

Medentika series of the medical device	**Manufacturer of the implant system**	**Compatible implant system**	**Implant Diameters (mm)**	**Platform Diameters (mm)**
EV-Series	DENTSPLY Implants	ASTRA TECH OsseoSpeed® EV	3.0	3.0
F-Series	Nobel Biocare	NobelActive® CC	3.0, 5.5	3.0, WP 5.5
OT-Series	OSSTEM Implant HiOssen Implant®	TS-System ET-System	3.5, 4.0, 4.5, 5.0, 6.0, 7.0 3.5, 4.0, 4.5, 5.0, 6.0, 7.0	Mini, Regular
S-Series	Dentsply Implants	ASTRA TECH OsseoSpeed® TX	3.0	3.0

Type of Use (Select one or both, as applicable)

☒Prescription Use (Part 21 CFR 801 Subpart D) ☐Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K223113

Device Name

Medentika CAD/CAM Abutments

Indications for Use *(Describe)*

Medentika PreFace CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

Medentika Preface is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center. The final patient matched form is a MedentiCAD abutment.

Medentika abutments for the Dentsply Sirona Astra Tech OsseoSpeed EV 3.0mm and TX 3.0mm implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

Implant System Compatibility Series (Series / Implant System / Implant diameter / Platform Diameters or Implant Connection):

Medentika series of the medical device	**Manufacturer of the implant system**	**Compatible implant system**	**Implant Diameters (mm)**	**Platform Diameters (mm)**
E-Series	Nobel Biocare	Replace™ Select	6.0	6.0
EV-Series	DENTSPLY Implants	ASTRA TECH OsseoSpeed® EV	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4
F-Series	Nobel Biocare	NobelActive® CC	5.5	WP 5.5
OT-Series	OSSTEM Implant HiOssen Implant®	TS-System ET-System	3.5, 4.0, 4.5, 5.0, 6.0, 7.0 3.5, 4.0, 4.5, 5.0, 6.0, 7.0	Mini, Regular

Type of Use *(Select one or both, as applicable)*

☒Prescription Use (Part 21 CFR 801 Subpart D) ☐Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

510(k) Number *(if known)*

K223113

Device Name

Medentika Multi-unit Abutments

Indications for Use *(Describe)*

Multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient.
Implant System Compatibility Series (Series / Implant System / Implant diameter / Platform Diameters or Implant Connection):

Medentika Series of the medical device	**Manufacturer of the implant system**	**Compatible implant system**	**Implant Diameters (mm)**	**Platform Diameters (mm)**
E-Series	Nobel Biocare	Replace Select™	3.5, 4.3, 5.0	NP 3.5, RP 4.3, WP 5.0
S-Series	DENTSPLY Implants	ASTRA TECH OsseoSpeed® TX	3.5, 4.0, 4.5, 5.0	3.5/4.3, 4.5/5.0
F-Series	Nobel Biocare	NobelActive® CC, NobelReplace® CC	3.5, 4.3, 5.0, 5.5	NP 3.5, RP 4.3/5.0, WP 5.5
OT-Series	OSSTEM Implant HiOssen Implant	TS System ET System	3.5, 4.0, 4.5, 5.0, 6.0, 7.0 3.5, 4.0, 4.5, 5.0, 6.0, 7.0	Mini, Regular

Type of Use *(Select one or both, as applicable)*

☒Prescription Use (Part 21 CFR 801 Subpart D) ☐Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC (on behalf of Medentika GmbH) 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052
	On the behalf of:
	Medentika GmbH Hammweg, 8-10 76549 Hügelsheim, Germany
Contact Person:	Jennifer M. Jackson, MS, RAC Sr. Director, Regulatory Affairs and Quality Phone Number: +1 978 747-2509 Fax Number: +1 978 747-0023
Prepared By & Alternate Contact:	Nadia Fouladi Head of Regulatory Affairs International Medentika GmbH Phone number: +4972296991210
Date Prepared:	April 15, 2024

Name of the Device

Trade Names:	Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM TiBases, Medentika Multi-unit Abutments
Common Name:	Dental implant abutment
Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR §872.3630
Device Classification:	II

Product Code(s): NHA

Classification Panel: Dental

Predicate and Reference Device(s)

Primary Predicate:

- K142167 – Medentika Abutment System

Reference Devices for Abutments:

- K150203 – Medentika CAD/CAM Abutments
- K170838 – Medentika CAD/CAM TiBases
- K191123 – Medentika Multi-Unit Abutment

Reference Devices to support added compatible implants:

- K130999 and K120414 – OsseoSpeed EV
- K101732 – OsseoSpeed TX
- K121995 and K161604 – TS System
- K140934 – ET System
- K142260 – NobelActive
- K020646 – Nobel Replace
- K061410 – Tapered Screw-Vent
- K073142 – NobelReplace CC

Device Description

The Medentika abutments include abutments, abutment screws, caps, and bases which are labelled under a specific Medentika series and are compatible with a specified dental implant system. The abutments include single-unit abutments intended for use with dental implants as a support for single or multiple tooth protheses in the maxilla or mandible of a partially or fully edentulous patient. The abutments also include multi-unit abutments

indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient.

The purpose of this premarket notification is to add additional abutments. The subject abutments include abutments compatible with additional dental implant systems forming a new Medentika series (the OT series). The subject abutments also include abutments compatible with new implant diameters in existing Medentika series (E, EV, F, and S). Lastly, the subject abutments include new abutment designs compatible with existing implant diameters in existing Medentika series (R).

Indications for Use and Summary of Similarities and Differences in Technological Characteristics, Performance Testing, and Intended Use

Medentika Standard and Temporary Abutments

The subject and existing Medentika standard and temporary abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. Table 1 includes the exact indications for use statements.

<table>
<tr><th>Comparison</th><th>Subject
Medentika Abutments - Standard abutment, temporary abutments, and MedentiLOC abutments</th><th>K142167
Medentika Abutment System</th></tr>
<tr><td>Indications for use</td><td>Medentika abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
Medentika abutments for the Dentsply Sirona Astra Tech OsseoSpeed EV 3.0mm and TX 3.0mm implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.
Implant System Compatibility Series (Series / Implant System / Implant diameter / Platform Diameters or Implant connection):
Standard Abutment:
<table>
<tr><td>Medentika series of the medical device</td><td>Manufacturer of the implant system</td><td>Compatible Implant system</td><td>Implant Diameters (mm)</td><td>Platform Diameters (mm)</td></tr>
<tr><td>EV-Series</td><td>DENTSPLY Implants</td><td>ASTRA TECH OsseoSpeed® EV</td><td>3.0, 3.6, 4.2, 4.8, 5.4</td><td>3.0, 3.6, 4.2, 4.8, 5.4</td></tr>
<tr><td>S-Series</td><td>DENTSPLY Implants</td><td>ASTRA TECH OsseoSpeed® TX</td><td>3.0</td><td>3.0</td></tr>
<tr><td>R-Series</td><td>ZimVie</td><td>Tapered Screw-Vent®</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
</table>
Temporary Abutment:
<table>
<tr><td>Medentika series of the medical device</td><td>Manufacturer of the implant system</td><td>Compatible Implant system</td><td>Implant Diameters (mm)</td><td>Platform Diameters (mm)</td></tr>
<tr><td>S-Series</td><td>DENTSPLY Implants</td><td>ASTRA TECH OsseoSpeed® TX</td><td>3.0</td><td>3.0</td></tr>
</table>
MedentiLOC Abutment:
<table>
<tr><td>Medentika series of the medical device</td><td>Manufacturer of the implant system</td><td>Compatible Implant system</td><td>Implant Diameters (mm)</td><td>Platform Diameters (mm)</td></tr>
<tr><td>OT-Series</td><td>OSSTEM Implant
HiOssen Implant</td><td>TS System

ET-System</td><td>3.5, 4.0, 4.5, 5.0, 6.0, 7.0
3.5, 4.0, 4.5, 5.0, 6.0, 7.0</td><td>Mini, Regular</td></tr>
</table></td><td>Medentika abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
Abutments are compatible with the following implant systems:
<table>
<tr><th>Implant System</th><th>Series</th><th>Implant Diameters (mm)</th></tr>
<tr><td>Nobel Biocare Replace Select</td><td>E-Series</td><td>3.5, 4.3, 5.0, 6.0</td></tr>
<tr><td>Nobel Biocare NobelActive</td><td>F-Series</td><td>3.5, 4.3, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite® Certain</td><td>H-Series</td><td>3.25, 4.0, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite</td><td>I-Series</td><td>3.25, 3.75, 4.0, 5.0</td></tr>
<tr><td>Nobel Biocare Branemark</td><td>K-Series</td><td>3.3, 3.75, 4.0, 5.0</td></tr>
<tr><td>Straumann Bone Level</td><td>L-Series</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>Straumann Standard</td><td>N-Series</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>Zimmer Tapered Screw-vent</td><td>R-Series</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td></tr>
<tr><td>Astra Tech OsseoSpeed</td><td>S-Series</td><td>3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Denstply Friadent Frialit/XiVE</td><td>T-Series</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
<tr><td>Dentsply Firadent Ankylos</td><td>Y-Series</td><td>3.5, 4.5, 5.5, 7.0</td></tr>
</table></td></tr>
</table>

Table 1 – Comparison of the Proposed and Previously Cleared Indications for use for the Medentika Standard and Temporary Abutments.

510(k) Summary

The design of the subject Medentika standard and temporary abutments is consistent with that of the previously cleared Medentika standard and temporary abutments. A detailed comparison of the subject and previously cleared Medentika standard and temporary abutments is included in Table 1.

Comparison	Subject Medentika abutments	K142167 Medentika abutment system	Equivalence
FDA Product Code	NHA	NHA	Equivalent
Series	R, S, EV	E, F, H, I, K, L, N, R, S, T	The EV series is a new series. Addition of abutments compatible with OsseoSpeed EV implants does not raise different questions of safety and effectiveness. Mechanical testing and engineering analyses demonstrate equivalency.
Abutment Designs	Standard abutment Temporary abutment	Standard abutment Temporary abutment	Equivalent
Prosthesis Attachment	Cement retained	Cement retained	Equivalent
Restoration	Single unit	Single unit	Equivalent
Compatible Implant Body Diameter (mm)	3.0-5.7	3.5-6	Addition of abutments compatible with Ø3.0mm implants do not raise different questions of safety and effectiveness. Mechanical testing and engineering analyses demonstrate equivalency.
Gingival Height (mm)	1-3.5	1-3	The increase in gingival height does not raise different questions of safety and effectiveness. Mechanical testing and engineering analyses demonstrate equivalency.
Abutment Angulation (degrees)	Straight, 16°, 18°	Straight, 16°, 18°, 21°	Equivalent
Abutment & Abutment Screw Materials	Ti6Al4V, medical grade 5, conforming to ASTM F136	Ti6Al4V, medical grade 5, conforming to ASTM F136	Equivalent

Comparison	Subject Medentika abutments	K142167 Medentika abutment system	Equivalence
Sterilization	Supplied non-sterile Moist heat sterilized by end user	Supplied non-sterile Moist heat sterilized by end user	Equivalent
Usage	Single-patient, single-use	Single-patient, single-use	Equivalent

Table 2 – Comparative Summary of the Proposed and the Previously Cleared Medentika Standard and Temporary Abutments

The Medentika MedentiLOC abutments are also part of the Medentika standard and temporary grouping of abutments. These abutments are designed for overdenture attachments. The design of the subject MedentiLOC abutments is consistent with that of the previously cleared MedentiLOC abutments. A detailed comparison of the subject and previously cleared MedentiLOC abutments is supplied in Table 3.

Comparison	Subject Medentika MedentiLOC	K142167 Medentika MedentiLOC	Equivalence
FDA Product Code	NHA	NHA	Equivalent
Series	OT	E, F, H, I, K, L, N, R, S, T, Y	The OT series is a new series. Addition of abutments compatible with OSSTEM Implants TS System and HiOssen Implants ET System implants does not raise different questions of safety and effectiveness. Mechanical testing and engineering analyses demonstrate equivalency.
Abutment Designs	Overdenture attachment abutments	Overdenture attachment abutments	Equivalent
Prosthesis Attachment	Patrices-Matrices	Patrices-Matrices	Equivalent

Comparison	Subject Medentika MedentiLOC	K142167 Medentika MedentiLOC	Equivalence
Restoration	Multi-unit (full or partial overdenture)	Multi-unit (full or partial overdenture)	Equivalent
Implant-Abutment Platform Diameter (mm)	3.5 – 7.0	3.4 – 7	Equivalent
Gingival Height (mm)	1-5	1-5	Equivalent
Abutment Angulation (degrees)	Straight	Straight, 15°	Equivalent
Abutment & Abutment screw materials	Ti6Al4V, medical grade 5, conforming to ASTM F136 Titanium nitride coating on abutments	Ti6Al4V, medical grade 5, conforming to ASTM F136 Titanium nitride coating on abutments	Equivalent
Sterilization	Supplied non-sterile Moist heat sterilized by end user	Supplied non-sterile Moist heat sterilized by end user	Equivalent
Usage	Single-patient, single-use	Single-patient, single-use	Equivalent

Table 3 – Comparative Summary of the Proposed and Previously Cleared Medentika MedentiLOC Abutments (part of the standard and temporary abutments grouping)

Medentika CAD/CAM TiBases

The subject and existing Medentika TiBase CAD/CAM abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. The two-piece abutment which compose the final abutment consists of the pre-manufactured titanium base component composed of titanium alloy and the CAD/CAM patient matched mesostructured (or superstructure) composed of zirconia. The CAD/CAM patient matched mesostructure (or superstructure) composed of zirconia is intended to be cemented to the pre-manufactured titanium base using Multilink® Hybrid Abutment Cement by Ivoclar Vivadent (K130436).

Table 4 includes the exact indications for use statements.

Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM TiBases, Medentika Multi-unit Abutments

510(k) Summary

<table>
<tr><th>Comparison</th><th>Subject
Medentika Titanium bases</th><th>K170838
Medentika Titanium bases</th><th>K150203
Medentika Titanium bases</th></tr>
<tr><td>Indications for use</td><td>Medentika TiBase CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
Medentika TiBase is intended for use with the Straumann® CARES® System. All digitally designed copings and/or crowns are intended to be sent to Straumann for manufacture at a validated milling center.
Medentika abutments for the Nobel Biocare Nobel Active®* 3.0mm, Dentsply Sirona Astra Tech OsseoSpeed EV®* 3.0mm and TX®* 3.0mm implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.
Implant System Compatibility Series (Series / Implant System / Implant diameter / Platform Diameters or Implant Connection):
<table>
<tr><th>Medentika Series</th><th>Manufacturer of the implant system</th><th>Compatible implant system</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>EV-Series</td><td>DENTSPLY Implants</td><td>ASTRA TECH OsseoSpeed® EV</td><td>3.0</td><td>3.0</td></tr>
<tr><td>S-Series</td><td>DENTSPLY Implants</td><td>ASTRA TECH OsseoSpeed® TX</td><td>3.0</td><td>3.0</td></tr>
<tr><td>F-Series</td><td>Nobel Biocare</td><td>Nobel Active® CC</td><td>3.0, 5.5</td><td>3.0, WP 5.5</td></tr>
<tr><td>OT-Series</td><td>OSSTEM Implant
HiOssen Implant</td><td>TS System
ET System</td><td>3.5, 4.0, 4.5, 5.0, 6.0, 7.0
3.5, 4.0, 4.5, 5.0, 6.0, 7.0</td><td>Mini, Regular</td></tr>
</table></td><td>Medentika TiBase CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Combability</th><th>Series</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>Nobel Biocare Replace Select</td><td>E</td><td>3.5, 4.3, 5.0, 6.0</td><td>3.5, 4.3, 5.0, 6.0</td></tr>
<tr><td>Dentsply® Implants/ASTRA TECH OsseoSpeed® EV</td><td>EV</td><td>3.6, 4.2, 4.8, 5.4</td><td>3.6, 4.2, 4.8, 5.4</td></tr>
<tr><td>Nobel Biocare NobelActive</td><td>F</td><td>3.5, 4.3, 5.0</td><td>3.5, 3.9(4.3), 3.9 (5.0)</td></tr>
<tr><td>Biomet 3i Osseotite Certain</td><td>H</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Nobel Biocare Branemark</td><td>K</td><td>3.3, 3.75, 4.0, 5.0</td><td>3.5, 4.1, 4.1, 5.1</td></tr>
<tr><td>Straumann Bone Level</td><td>L</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>Straumann Soft Tissue Level</td><td>N</td><td>3.3, 4.1, 4.8</td><td>3.5 (NNC), 4.8, 6.5</td></tr>
<tr><td>Zimmer Tapered Screw-vent</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
</table></td><td>Medentika TiBase CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Combability</th><th>Series</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>Nobel Biocare Replace™ Select</td><td>E</td><td>3.5, 4.3, 5.0, 6.0</td><td>3.5, 4.3, 5.0, 6.0</td></tr>
<tr><td>Nobel Biocare NobelActive™</td><td>F</td><td>3.5, 4.3, 5.0</td><td>3.5, 3.9(4.3), 3.9 (5.0)</td></tr>
<tr><td>Biomet 3i® Osseotite Certain®</td><td>H</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Nobel Biocare Branemark</td><td>K</td><td>3.3, 3.75, 4.0, 5.0</td><td>3.5, 4.1, 4.1, 5.1</td></tr>
<tr><td>Straumann Bone Level</td><td>L</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>Straumann Soft Tissue Level</td><td>N</td><td>3.3, 4.1, 4.8</td><td>3.5 (NNC), 4.8, 6.5</td></tr>
<tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td>Astra Tech OsseoSpeed™</td><td>S</td><td>3.5, 4.0, 4.5, 5.0</td><td>3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Denstply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
<tr><td>Dentsply Firadent® Ankylos®</td><td>Y</td><td>3.5, 4.5, 5.5, 7.0</td><td>3.5, 4.5, 5.5, 7.0</td></tr>
</table></td></tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td>
<table>
<tr><td>Astra Tech OsseoSpeed</td><td>S</td><td>3.5, 4.0, 4.5, 5.0</td><td>3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Denstply Friadent Frialit/XiVE</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
<tr><td>Dentsply Firadent Ankylos</td><td>Y</td><td>3.5, 4.5, 5.5, 7.0</td><td>3.5, 4.5, 5.5, 7.0</td></tr>
</table>
Medentika TiBase is intended for use with the Straumann® CARES® System. All digitally designed copings and/or crowns are intended to be sent to Straumann for manufacture at a validated milling center.
</td>
<td>Medentika TiBase is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.</td>
</tr>
</table>

Table 4 – Comparison of the proposed and previously cleared indications for use for the Medentika Ti Base CAD/CAM abutments

The design of the subject Medentika TiBase CAD/CAM abutments is consistent with that of the previously cleared Medentika TiBase CAD/CAM abutments. A detailed comparison of the subject and previously cleared Medentika TiBase CAD/CAM abutments is included in Table 5.

Comparison	Subject Medentika Titanium bases	K170838 Medentika Titanium bases	K150203 Medentika Titanium bases	Equivalence
FDA product code	NHA	NHA	NHA	Equivalent
Series	EV, F, OT, S	E, EV, F, H, I, K, L, N, R, S, T, Y	E, F, H, I, K, L, N, R, S, T, Y	The OT series is a new series. Addition of abutments compatible with OSSTEM Implants TS System and HiOssen ET System implants does not raise different questions of safety and effectiveness. Mechanical testing and engineering analyses demonstrate equivalency.
Abutment Designs	Titanium Base 2nd Generation Titanium Base Angled Screw Channel (ASC) Flex	Titanium Base 2nd Generation	Titanium Base 1st Generation Titanium Base 2nd Generation	Equivalent
Prosthesis Attachment	Cement retained	Cement retained	Cement retained	Equivalent
Restoration	Single unit	Single unit	Single unit	Equivalent
Compatible Implant Body Diameter (mm)	3.0-7.0	3.3-6.0	3.3 -6.0	Addition of abutments compatible with Ø3.0mm and Ø7.0mm implants does not raise different questions of safety and effectiveness. Mechanical testing and engineering analyses demonstrate equivalency.
Gingival Height (in the Titanium base) (mm)	0.65-1.2	0.1-1.15	0.1-1.15	Equivalent
Titanium Component Angulation	Straight	Straight	Straight	Equivalent
Abutment & Abutment Screw Materials	**Ti6Al4V, medical grade 5, conforming to ASTM F136**	**Ti6Al4V, medical grade 5, conforming to ASTM F136**	**Ti6Al4V, medical grade 5, conforming to ASTM F136**	Equivalent
Sterilization	**Supplied non-sterile** Moist heat sterilized by end user	**Supplied non-sterile** Moist heat sterilized by end user	**Supplied non-sterile** Moist heat sterilized by end user	Equivalent
Usage- All components	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Equivalent
Limits				
Superstructure Material	Zirconia	Zirconia and IPS e.max CAD	Zirconia	Equivalent
Minimum wall thickness (mm)	0.5	0.4 (0.9 for IPS e.max CAD)	0.4	Equivalent
Minimum abutment post height for single-unit restorations (mm) (length above the abutment collar/gingival height)	4.0	4.0	4.0	Equivalent

Comparison	Subject Medentika Titanium bases	K170838 Medentika Titanium bases	K150203 Medentika Titanium bases	Equivalence
Minimum gingival height (mm)	0.65	0.1	0.1	Equivalent
Maximum height of the emergence profile (mm)	5	5	5	Equivalent
Maximum Abutment Angulation (degrees)	30°	30°	30°	Equivalent
Bonding cement	Multilink® Hybrid Abutment Cement by Ivoclar Vivadent K130436	Multilink® Hybrid Abutment Cement by Ivoclar Vivadent K130436	Multilink® Hybrid Abutment Cement by Ivoclar Vivadent K130436	Equivalent

Table 5 – Comparative Summary of the Proposed and the Previously Cleared Medentika TiBase CAD/CAM Abutments

Medentika Preface CAD/CAM Abutments

The subject and existing Medentika Preface CAD/CAM abutments, ti-blank abutment as patient matched abutments, are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. Table 6 includes the exact indications for use statements.

<table>
<tr><th>Comparison</th><th>Medentika Preface CAD/CAM abutments</th><th>K150203
Medentika Preface Abutments</th></tr>
<tr><td>Indications for use</td><td>Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth protheses in the maxilla or mandible of a partially or fully edentulous patient.
Medentika Preface is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center. The final patient matched form is a MedentiCAD abutment.
Medentika abutments for the Dentsply Sirona Astra Tech OsseoSpeed EV 3.0mm and TX 3.0mm implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.
Implant System Compatibility Series (Series / Implant System / Implant diameter / Platform Diameters or Implant Connection):
<table>
<tr><th>Medentika Series of the medical device</th><th>Manufacturer of the implant system</th><th>Compatible implant system</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>E-Series</td><td>Nobel Biocare</td><td>Replace™ Select</td><td>6.0</td><td>6.0</td></tr>
<tr><td>EV-Series</td><td>DENTSPLY Implants</td><td>ASTRA TECH OsseoSpeed® EV</td><td>3.0, 3.6, 4.2, 4.8, 5.4</td><td>3.0, 3.6, 4.2, 4.8, 5.4</td></tr>
<tr><td>F-Series</td><td>Nobel Biocare</td><td>NobelActive® CC</td><td>5.5</td><td>WP 5.5</td></tr>
<tr><td>OT-Series</td><td>OSSTEM Implants

HiOssen Implants</td><td>TS System

ET System</td><td>3.5, 4.0, 4.5, 5.0, 6.0, 7.0
3.5, 4.0, 4.5, 5.0, 6.0, 7.0</td><td>Mini, Regular</td></tr>
</table></td><td>Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth protheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Combability</th><th>Series</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>Nobel Biocare Replace™ Select</td><td>E</td><td>3.5, 4.3, 5.0, 6.0</td><td>3.5, 4.3, 5.0, 6.0</td></tr>
<tr><td>Nobel Biocare Nobel Active™</td><td>F</td><td>3.0, 3.5, 4.3, 5.0</td><td>3.0, 3.5, 3.9(4.3), 3.9 (5.0)</td></tr>
<tr><td>Biomet 3i Osseotite® Calcium®</td><td>H</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Nobel Biocare Branemark</td><td>K</td><td>3.3, 3.75, 4.0, 5.0</td><td>3.5, 4.1, 4.1, 5.1</td></tr>
<tr><td>Straumann Bone Level</td><td>L</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>Straumann Standard</td><td>N</td><td>3.3, 4.1, 4.8</td><td>3.5 (NNC), 4.8, 6.5</td></tr>
<tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td>Astra Tech OsseoSpeed™</td><td>S</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Denstply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
</table>
Medentika Preface is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.</td></tr>
</table>

Table 6 – Comparison of the proposed and previously cleared indications for use for the Medentika Preface CAD/CAM abutments

The design limits of the subject Medentika Preface CAD/CAM abutments are consistent with that of the previously cleared Medentika Preface CAD/CAM abutments. A detailed comparison of the subject and previously cleared Medentika Preface CAD/CAM abutments is included in Table 7.

Comparison	Medentika Preface CAD/CAM abutments	K150203 Medentika Preface Abutments	Equivalence
FDA product code	NHA	NHA	Equivalent
Series	E, EV, F, OT	E, F, H, I, K, L, N, R, S, T	The EV and OT series are new series. Addition of abutments compatible with OsseoSpeed EV, TS System, and ET System implants does not raise different questions of safety and effectiveness. Mechanical testing and engineering analyses demonstrate equivalency.
Abutment Designs	Titanium blank Ø11.5 and 16mm	Titanium blank Ø11.5 and 16mm	Equivalent
Prosthesis Attachment	Cement retained	Cement retained	Equivalent
Restoration	Single unit	Single unit	Equivalent
Compatible Implant Body Diameter (mm)	3.0-7.0	3.0-6.5	Addition of abutments compatible with Ø7.0mm implants does not raise different questions of safety and effectiveness. Mechanical testing and engineering analyses demonstrate equivalency.
Abutment & Abutment Screw Materials	Ti6Al4V, medical grade 5, conforming to ASTM F136	Ti6Al4V, medical grade 5, conforming to ASTM F136	Equivalent
Sterilization	**Supplied non-sterile** Moist heat sterilized by end user	**Supplied non-sterile** Moist heat sterilized by end user	Equivalent
Usage- All components	**Single-patient, single-use**	**Single-patient, single-use**	Equivalent
Limits			
Minimum wall thickness (mm)	0.4	0.4	Equivalent
Minimum gingival height in stock component (mm)	0.1-0.25	0.00-0.23	Equivalent Labeling includes specific warnings for gingival heights less than 0.5mm

Comparison	Medentika Preface CAD/CAM abutments	K150203 Medentika Preface Abutments	Equivalence
Maximum height of the emergence profile (mm)	5	5	Equivalent
Max angulation (degrees)	30°	30°	Equivalent
Minimum abutment post height (mm) (length above the abutment collar/gingival height)	4.0	4.0	Equivalent

Table 7 – Comparative Summary of the Proposed and Previously Cleared Medentika Preface CAD/CAM abutments

Medentika Multi-unit abutments

The subject and existing multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient. Table 8 includes the exact indications for use statements.

<table>
<tr><th>Comparison</th><th>Subject
Multi-unit Abutments</th><th>K191123
Multi-unit Abutments</th></tr>
<tr><td>Indications for use</td><td>Multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient.
Compatibility Series (Series / Implant System / Implant diameter / Platform Diameters or Implant Connection):
<table>
<tr><th>Medentika Series of the medical device</th><th>Manufacturer of the implant system</th><th>Compatible implant system</th><th>Implant Diameters (mm)</th><th>Platform Diameters (mm)</th></tr>
<tr><td>E-Series</td><td>Nobel Biocare</td><td>Replace Select™</td><td>3.5, 4.3, 5.0</td><td>NP 3.5, RP 4.3, WP 5.0</td></tr>
<tr><td>S-Series</td><td>DENTSPLY Implants</td><td>ASTRA TECH OsseoSpeed® TX</td><td>3.5, 4.0, 4.5, 5.0</td><td>3.5/4.3, 4.5/5.0</td></tr>
<tr><td>F-Series</td><td>Nobel Biocare</td><td>NobelActive® CC, NobelReplace® CC</td><td>3.5, 4.3, 5.0, 5.5</td><td>NP 3.5, RP 4.3/5.0, WP 5.5</td></tr>
<tr><td>OT-Series</td><td>OSSTEM Implant
HiOssen Implant</td><td>TS System
ET System</td><td>3.5, 4.0, 4.5, 5.0, 6.0, 7.0
3.5, 4.0, 4.5, 5.0, 6.0, 7.0</td><td>Mini, Regular</td></tr>
</table></td><td>Multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient.
Multi-unit Abutments are used for the restoration of the following dental implant systems:
<table>
<tr><td>Medentika series</td><td>Medentika series</td><td>Implant diameter</td><td>Platform diameter</td></tr>
<tr><td>EV-Series</td><td>Dentsply® Implants – ASTRA TECH OsseoSpeed®</td><td>3.6, 4.2, 4.8</td><td>3.6, 4.2, 4.8</td></tr>
<tr><td>F-Series</td><td>Nobel Biocare Nobel Active – NobelReplace Conical</td><td>3.5, 4.3, 5.0</td><td>NP 3.5, RP 4.3/5.0</td></tr>
<tr><td>H-Series</td><td>Biomet 3i - Certain</td><td>3.25, 4.0</td><td>3.4, 4.1</td></tr>
<tr><td>L-Series</td><td>Straumann - Bone Level</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>N-Series</td><td>Straumann – Soft Tissue Level</td><td>4.1, 4.8</td><td>4.8, 6.5</td></tr>
<tr><td>R-Series</td><td>Zimmer Dental Tapered Screw-vent</td><td>3.3, 3.7, 4.1, 4.7</td><td>3.5, 4.5</td></tr>
</table></td></tr>
</table>

Table 8 – Comparison of the proposed and previously cleared indications for use for the Medentika multi-unit abutments

The design of the subject Medentika multi-unit abutments is consistent with that of the previously cleared Medentika multi-unit abutments. A detailed comparison of the subject and previously cleared multi-unit abutments is supplied in Table 9.

Comparison	Subject Multi-unit Abutments	K191123 Multi-unit Abutments	Equivalence
FDA Product Code	NHA	NHA	Equivalent
Series	E, F, OT, S	EV, F, H, L, N, R	The E, OT, and S series are new series. Addition of abutments compatible with, Replace Select, Astra Tech OsseoSpeed TX, TS System, and ET System implants do not raise different questions of safety and effectiveness. Mechanical testing and engineering analyses demonstrate equivalency.
Abutment Designs	Multi-unit abutments base for construction of bridge and bar constructs	Multi-unit abutments base for construction of bridge and bar constructs	Equivalent
Prosthesis Attachment	For prosthetic restoration Cast-on procedures: Multi-unit Gold alloy cap castable CAD/CAM and traditional workflows: Multi-unit titanium base Cementable procedures: Multi-unit titanium caps Bridge screw Cover cap (temporary device)	For prosthetic restoration Cast-on procedures: Multi-unit Cobalt chromium alloy cap castable Multi-unit Gold alloy cap castable CAD/CAM and traditional workflows: Multi-unit titanium base Cementable procedures: Multi-unit titanium caps Bridge screw Cover cap (temporary device)	Equivalent
Restoration	Multi-unit	Multi-unit	Equivalent
Implant-Abutment Platform Diameter (mm)	3.5-7.0	3.25 – 5	Addition of abutments compatible with Ø7.0mm TS and ET System implants do not raise different questions of safety and effectiveness. Mechanical testing demonstrates equivalency.
Gingival Height (mm)	0.6-5.5	0.6-5.5	Equivalent
Abutment Angulation (degrees)	Straight, 17°, 30°	Straight, 17°, 30°	Equivalent
Abutment & Abutment Screw Materials	Ti6Al4V, medical grade 5, conforming to ASTM F136	Ti6Al4V, medical grade 5, conforming to ASTM F136	Equivalent

Comparison	Subject Multi-unit Abutments	K191123 Multi-unit Abutments	Equivalence
Sterilization	Supplied sterile Gamma irradiation	Supplied sterile Gamma irradiation	Equivalent
Usage	Single-patient, single-use	Single-patient, single-use	Equivalent
Packaging	Medical grade polyethylene blister with a sealing lid	Medical grade polyethylene blister with a sealing lid	Equivalent

Table 9 – Comparative Summary of the Proposed and Previously Cleared Medentika Multi-unit abutment

Materials

The subject abutments are manufactured from Ti6Al4V, medical grade 5, conforming to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI Alloy for Surgical Implant Applications. The multi-unit gold alloy castable caps are manufactured from gold alloy which meets applicable requirements defined in ISO 22674, Dentistry - Metallic materials for fixed and removable restorations and appliances. The MedentiLOC abutments have a titanium nitride coating.

Performance Testing

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence in this 510(k) includes:

- Dynamic fatigue testing according to the FDA guidance document Guidance for industry and FDA staff – class II special controls guidance document: root-form endosseous dental implants and endosseous dental abutments and ISO 14801 Dentistry — implants — dynamic loading test for endosseous dental implants,
- Dimensional analysis and reverse engineering of the implant-to-abutment connection platform were performed, including an assessment of maximum and minimum dimensions of critical design aspects, tolerances, and cross-sectional images of the submission device and compatible OEM implant body, OEM abutment, and OEM fixation screw. The testing demonstrated implant to abutment compatibility and has established substantial equivalency of the proposed device with predicate devices.

- Referenced from K191123 was steam sterilization validation according to ISO 17665-1: Sterilization of health care products – Moist heat – Part 1: Development, validation and routine control of a sterilization process for medical devices and ISO/TS 17665-2: Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1,
- Referenced from K191123 was gamma irradiation validation according to ISO 11137-1: Sterilization of health care products –Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, and ISO 11137-2:2013, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose,
- Referenced from K191123 was sterile packaging validation in accordance with ISO 11607-1: Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems and ISO 11607-2 Packaging for terminally sterilized medical devices- Part 2: Validation requirements for forming, sealing and assembly processes and,
- Referenced from K142167, K170838, K191123, K150203 and K061804 were biocompatibility evaluations in accordance with ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- Referenced from K180564 was MR testing in accordance with ASTM F2052-15, ASTM F2213-06 (2011), ASTM F2182-11a and ASTM F2119-13.

Conclusion

The data included in this submission demonstrate substantial equivalence to the predicate device listed above. Performance testing and comparison to previous clearances show that the subject devices are substantially equivalent.